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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,625	09/22/2003	Nalini M. Rajamannan	07039-163003	1186
26191	7590	04/20/2005	EXAMINER	
FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022			NGUYEN, QUANG	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/667,625	RAJAMANNAN, NALINI M.
	<b>Examiner</b>	<b>Art Unit</b>
	Quang Nguyen, Ph.D.	1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 25 January 2005.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 34-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 34-43 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

Applicants' amendment filed on 1/25/05 has been entered.

Amended claims 24-35 and new claims 36-43 are pending in the present application, and they are examined on the merits herein.

### ***Response to Amendment***

The rejection under 35 U.S.C. 102(b) as being anticipated by Choy et al. as evidenced by Dunstan et al. is withdrawn in light of Applicants' amendment.

The rejection under 35 U.S.C. 102(b) as being anticipated by Johnson et al. as evidenced by Kunkle, Jr. is withdrawn in light of Applicants' amendment.

### ***Claim Objections***

Claim 38 is objected to because the term "LDL" should be spelled out in full at the first occurrence of the term. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. ***This is a new ground of rejection necessitated by Applicants' amendment.***

Amended claim 34 recites "determining whether or not said test compound reduced the proliferation of said cells and whether or not said test compound increased nitric oxide synthase activity in said cells, wherein the reduction of proliferation and the increase in nitric oxide synthase activity indicates that said compound is an inhibitor of heart valve degeneration". Amended claim 35 recites "determining whether or not said drug induced proliferation of said cells and whether or not said drug increased nitric oxide synthase activity in said cells, wherein the induction of proliferation and the absence of an increase in nitric oxide synthase activity indicates that said drug promotes heart valve degeneration". There is literally no support in the originally filed specification for the step of determining whether or not a test compound increased nitric oxide synthase activity together with the determination whether or not the test compound reduced the proliferation in heart valve cells for a method of identifying an inhibitor of heart valve degeneration. Similarly, there is no written support in the originally filed specification for the step of determining whether or not a drug increased nitric oxide synthase activity together with the determination whether or not the drug induced proliferation of heart valve cells for a method of determining the safety of a drug. On the contrary, the specification teaches specifically a method for indentifying an inhibitor of heart valve degeneration in which a test compound is determined whether or not it reduced the proliferation of heart valve cells, and where the reduction of

proliferation indicates that the test compound is an inhibitor of heart valve degeneration, without any requirement or contemplation of determining of whether the test compound also increased nitric oxide synthase activity in heart valve cells (see page 4, lines 15-19; page 19, line 9 continues to line 11 of page 20). The specification also discloses specifically that a method for determining the safety of a drug involves simply the determination whether or not the drug induced proliferation of heart valve cells, and where the induction of proliferation indicates that the drug promotes heart valve degeneration, without any requirement or contemplation of determining whether the drug also increased nitric oxide synthase activity in heart valve cells (page 4, lines 20-23; page 20, lines 12-18). Applicants failed to point out the specific page number(s) and line number(s) that support for the amended steps in the methods as claimed. Page 24, lines 3-4 simply disclose in general a method for assessing nitric oxide synthase activity in aortic valve endothelial cell lysates using an NADPH disphorase reaction, without any specific teachings that the assay is also used in a method for identifying an inhibitor of heart valve degeneration or a method for determining the safety of a drug.

Therefore, given the lack of guidance provided by the originally filed specification, it would appear that Applicants did not contemplate or have possession of the claimed invention at the time the application was filed.

### ***Conclusion***

***No claims are allowed.***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Irem Yucel, Ph.D., at (571) 272-0781.

**To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636; Central Fax No. (571) 273-8300.**

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image

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problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

Quang Nguyen, Ph.D.

  
DAVID GUZO  
PRIMARY EXAMINER